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The UCLA-Community Breast Cancer Collaborative

Clinical Translational Research Program

DAMD17-01-1-0180

Introduction Breast cancer remains a serious disease in the United States. Recently, advances in molecular and cell biology have identified specific targets and strategies for the treatment and prevention of breast cancer. The rapid translation of these advances into clinical trials is imperative for three reasons. First, some of these strategies will be effective in decreasing the incidence, morbidity, or mortality of breast cancer. The more rapidly women enter the clinic, the more they will benefit. Second, patients with breast cancer desire and deserve access to these novel treatments, particularly when standard approaches have been exhausted. Finally, clinical trials provide information that compliments basic research and advances the understanding of the disease. The majority of patients with breast cancer are cared for in the community. Although many community physicians are committed to advancing the field, the infrastructure to support translational trials of novel treatment or prevention strategies does not exist in the community setting. Moreover, few academic cancer centers have forged meaningful partnerships with consortia of community physicians to provide them with the laboratory interface and statistical and regulatory support required for good translational clinical research.

Objective Our hypothesis has been that four elements are required to exploit the opportunities provided by recent advances: (1) the development of consortia of community physicians committed to the study of novel approaches to the treatment and prevention of breast cancer; (2) the provision of an infrastructure composed of clinical trials personnel; (3) the involvement of an academic center committed to community-based research and possessed of expertise in basic research, statistics, data management, and regulatory support; and (4) partnerships with pharmaceutical companies involved in the discovery and manufacture of novel agents. Since the initiation of this infrastructure award, we have continued to expand on our previous success in the UCLA-Community Oncology Research Network (UCLA-CORN) through: 1)

the recruitment of additional research sites, increasing access for women from underserved populations, 2) the initiation of translational research protocols relevant to the breast cancer problem and 3) an overall increase in accrual to breast cancer research protocols in the UCLA-CORN.

Specific Aims Our specific aims have included: 1) To build upon a pre-exusting network of community physicians committed to clinical research; (2) to provide them with an infrastructure specifically devoted to translational research in breast cancer; (3) to make these studies of novel treatment and prevention strategies available to an ethnically diverse population; and (4) to increase the number of new strategies tested and the accessibility of these studies to women in our region.

To approach these goals, we have utilized this infrastructure award to build upon the UCLA-CORN through the addition of practices that include a large proportion of African American, Hispanic, Asian, and Pacific Islander patients. We have recruited, trained and employed support research staff specifically focused on accrual to new studies of novel therapeutic and prevention strategies for breast cancer. This enhanced network remains centered in the UCLA Jonsson Comprehensive Cancer Center, which continues to provide statistical and regulatory support, as well as a basic science interface that works with the pharmaceutical industry to provide novel agents for translation.

Five studies were proposed for the initial year of this infrastructure program, including: (1) combined biological antiangiogenesis therapy; (2) combined antiangiogenesis and cytotoxic therapy; (3) epidermal growth factor receptor blockade; (4) farnesyl-transferase inhibitor therapy; and (5) risk reduction utilizing a low fat, fish oil supplemented diet with measurement of relevant intermediate markers. One of these studies, that involving the farnesyl-transferase inhibitor strategy, has not yet been started. The remaining four have been opened to accrual, and one, the fish oil/prevention trial, has completed accrual.

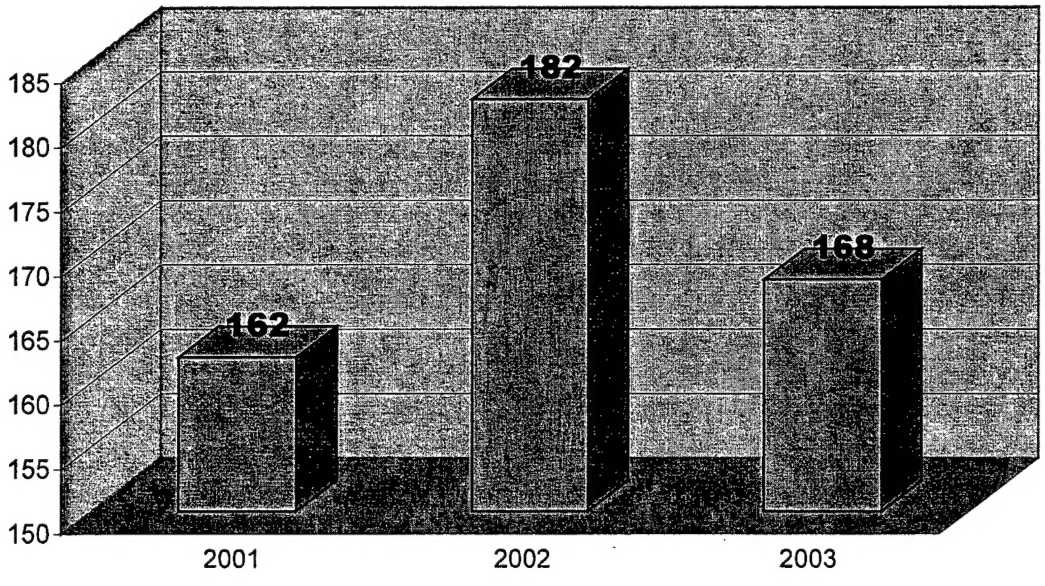
Relevance The program has already supported the testing of four additional novel strategies for the prevention or treatment of breast cancer. We expect this rate to remain relatively constant, and to achieve our initial target of testing several new strategies per year for three years. The testing will continue to involve a representative cross-section of women in the United States. Given the promise inherent in advances in our understanding of the pathogenesis of this disease, rapid clinical translation is likely to decrease the morbidity and mortality associated with

this disease by providing better options than currently exist for prevention and treatment.

Progress

Figure 1 represents the number of patients accrued. The funding provided by this award, supplied additional specific personnel that are solely devoted to the accrual of possible study patients. The decline on the accrual of patients in the 2003 fiscal year was due to the closure of several clinics due to lack of participation in patient enrollment. The number projected for the 2004 fiscal year is a lot higher due to a number of reasons including: wider range of research studies available for breast cancer patients and the addition of several network sites to the UCLA Oncology Network including:

1. Atlanta, Georgia
2. Augusta, Georgia
3. Macon, Georgia
4. Marietta I and II, Georgia
5. Roswell, Georgia
6. Orlando, Florida



Current breast cancer studies open in the UCLA-CORN Network

Tittle	Principal Investigator
Clinical Protocol for Evaluation of the Bayer Immuno 1 Her-2/neu Assay and the Oncogenes Science Microtiter ELISA Her-2/neu Assay for use in the Management of Patients with Breast Cancer on Herceptin Therapy.	Dennis Slamon, MD
Phase III A Multicenter Randomized Trial Comparing Docetaxel (Taxotere) and Trastuzumab (Herceptin) with Docetaxel (Taxotere) Platinum Salt (Cisplatin or Carboplatin) and Trastuzumab (Herceptin) as First Line Chemotherapy for Patients with Advanced Breast Cancer Containing the HER2 Gene Amplification. (BCIRG 007)	Linnea Chap, MD
Phase I/II Study of Herceptin Combined with OSI-774 in the Fisrt-Line Treatment of Metastatic Breast Cancer Associated with HER2/neu Overexpression.	Carolyn Britten, MD
A Phase II Study of Bi-Weekly Docetaxel as First Line Therapy for Metastatic Breast Cancer.	Mark, Pegram, MD
An Open-Label Multicenter, Single Arm Phase II Study of Oral GW572016 As Single Agent Therapy in Subjects with Advanced or Metastatic Breast Cancer Who Have Progressed While Receiving Herceptin Containing Regimens	Mark Pegram, MD
An Open-Label Multicenter, Single Arm Phase II Study of Oral GW572016 As Single Agent Therapy in Subjects with Advanced or Metastatic Breast Cancer Who Have Progressed While Receiving Herceptin Containing Regimens (EGF 20008)	Mark Pegram, MD
Neoadjuvant treatment and Molecular Characterization of Locally Advanced Breast Cancer	Helena Chang, MD

Summary Since the last report, the infrastructure award have made continuous progress towards achieving the program's goals. Ever since the funding of this award, the addition of breast cancer translational research studies that provide access for under-represented populations has been possible and thus having a great impact in the overall clinical trial accrual.